

K 113674



A HENRY SCHEIN® COMPANY

510(K) SUMMARY:

- a- Submitted by:** HANDPIECE HEADQUARTERS
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Tel. 714-579-0175 Fax. 714-579-0186
- b- Contact person:** Tina Steffanie-Oak, Tel. 717-335-7230, ext. 4150
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c- Date summary prepared: 04/2/2012**d- Device Name:**

- Common Name:** Dental Handpiece and Accessories, Dental Handpiece Cleaner and Lubricant.
- Trade Name:** Spray & Clean Handpiece Cleaner & Lubricant
Maxima Handpiece Cleaner & Lubricant
EZCARE Handpiece Cleaner & Lubricant
(3 trade names carry the same chemical formula)
- Common Name:** Dental Handpiece and Accessories, Dental Handpiece Lubricant.
- Trade Name:** Maxima Handpiece Lubricant

Classification Name: Class I Device, 21 CFR 872.4200, Handpiece, Air-power
Dental, EFB

- e- Substantial Equivalency is claimed against the following devices:**
PANA SPRAY lubricant oil by NSK America Corp.- K052700

f- Description of the device:

Dental Handpiece Cleaner and Lubricant (Spray & Clean Handpiece Cleaner & Lubricant, Maxima Handpiece Cleaner & Lubricant, and EZcare Handpiece Cleaner & Lubricant).

This is an aerosol product that is used during routine maintenance. It contains two major components, which are Mineral oil and Isopropyl Alcohol. The product lubricates and cleans dental handpieces and air motors when sprayed directly into the air drive tube. It lubricates and cleans out contamination from all internal parts, such as the bearings, gears and auto chucks.

Dental Handpiece Lubricant: Maxima Handpiece Lubricant

Maxima Handpiece Lubricant contains mineral oil that drops directly into the air drive tube of the dental handpiece. When the user operates the handpiece, the pressure of air in the air drive tube will deliver the oil into the handpiece to lubricate the bearings, gears, and auto chucks.

g- Statement of Intended Use:

The Dental Handpiece Cleaner and Lubricant is intended to be used during routine maintenance in order to lubricate and clean air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.

The Dental Handpiece Lubricant is intended to be used during routine maintenance in order to lubricate air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.

h – Device and Predicate Comparison Table:

Descriptive Information	Subject Device: Spray & Clean Handpiece Cleaner & Lubricant, Maxima Handpiece Cleaner & Lubricant, and EZCARE Handpiece Cleaner & Lubricant Maxima Handpiece Lubricant	Predicate: NSK PANA SPRAY LUBRICANT OIL SUPERIOR CLEANING & LUBRICANT NSK PANA SPRAY LUBRICANT OIL SUPERIOR CLEANING & LUBRICANT
Indication of use	The Dental Handpiece Cleaner and Lubricant is intended to be used during routine maintenance in order to lubricate and clean air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization. The Dental Handpiece Lubricant is intended to be used during routine maintenance in order to lubricate air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.	This new device is a lubricant and is intended for use to clean and lubricate the dental and medical surgical handpieces.
Components name/ Weight percentage (% w/w)	Spray & Clean Handpiece Cleaner & Lubricant, Maxima Handpiece Cleaner & Lubricant, and EZCARE Handpiece Cleaner & Lubricant (3 trade names carry the same chemical formula) Propellant: (84% w/w) Propane 7.5% n-Butane 17.5% Isopropanol 59%	PANA SPRAY Propellant: (63% w/w) Propane Isobutane n-Butane Isopentane

	Lubricant: (16% w/w) Mineral oil 16% Hydrocarbon Range C16-C28 0% Maxima Handpiece Lubricant Lubricant: (100% w/w) Severely refined Mineral oil 100% Hydrocarbon Range C16-C28 0%	Lubricant: (16% w/w) Petroleum Oil Hydrocarbon Range C16-C28 Lubricant: (16% w/w) Petroleum Oil Hydrocarbon Range C16-C28
Fragrance	N/A	N/A

Physical Property comparison table:

Physical property	Predicate Device: Pana Spray Lubricant Oil	Subject Device: Spray & Clean Handpiece Cleaner and Lubricant	Subject Device: Maxima Handpiece Lubricant
Physical State	Aerosol Product	Aerosol Product	Transparent Water- white Liquid
Color	clear	Clear	Clear
Solubility in Water	Insoluble	Insoluble	Insoluble
Specific Gravity	0.63 (H ₂ O=1)	.70-.90 g/cc	0.835 @ 15.6 °C (H ₂ O=1)
Boiling Point	-44 deg F-31 deg F	Propellant: 7.29 °F Concentrate: 180 °F	310 °C (590 °F)
Viscosity	n/a	n/a	n/a

i – Description of Non-Clinical Test Data used to support SE Decision:

The table below provides a general summary of the performance testing which was conducted on the subject devices and the predicate device. The testing results indicate that the subject devices meet their design performance requirements.

Comparison	Test	Method	Conclusion
Spray & Clean Handpiece Cleaner & Lubricant vs. NSK Pana Spray	Handpiece Performance Cycle Testing	Bur extraction force, concentricity, noise level, and torque	Met handpiece performance specification
Maxima Handpiece Lubricant vs. NSK Pana Spray	Handpiece Performance Cycle Testing	Bur extraction force, concentricity, noise level, and torque	Met handpiece performance specification

j – Description of Clinical Test Data used to support SE Decision:

Clinical test data was not required to support our substantial equivalence determination.

k – Conclusions Drawn from Non-Clinical Data:

Based on the information provided in this submission Handpiece Headquarters believes that the Dental Handpiece Cleaner & Lubricant and Dental Handpiece Lubricant are intended for the same use and are substantially equivalent to the predicate devices identified.

I – Biocompatibility: Biocompatibility testing has not been conducted on the subject devices, because the chemical components have already been incorporated in legally marketed devices with similar conditions of use and have a demonstrated history of biocompatibility.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Tina Steffanie-Oak
Consultant
Handpiece Headquarters Inc, - HPR Inc.
620 S. Placentia Avenue
Placentia, California 92870

APR - 5 2012

Re: K113674

Trade/Device Name: Dental Handpiece Cleaner and Lubricant, and a Dental Handpiece Lubricant (sold under these brand names Spray & Clean Handpiece Cleaner & Lubricant, Maxima Handpiece Cleaner & Lubricant, EZcare Handpiece Cleaner & Lubricant, and Maxima Handpiece Lubricant)

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: I

Product Code: EFB

Dated: April 2, 2012

Received: April 3, 2012

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113674

Device Name: Dental Handpiece Cleaner and Lubricant, and a Dental Handpiece Lubricant (sold under these brand names Spray & Clean Handpiece Cleaner & Lubricant, Maxima Handpiece Cleaner & Lubricant, EZcare Handpiece Cleaner & Lubricant, and Maxima Handpiece Lubricant)

Indications for Use:

The Dental Handpiece Cleaner and Lubricant is intended to be used during routine maintenance in order to lubricate and clean air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.

The Dental Handpiece Lubricant is intended to be used during routine maintenance in order to lubricate air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.

Prescription Use X
(Per 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 801

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pheralman for MSR
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K113674